SEP 21 2000

CRITIKON VITAL ANSWERS™

K002248

SUMMARY OF SAFETY AND EFFECTIVENESS

July 18 ,2000

DINAMAP® Pro 1000 Monitor

A. Submitter

Critikon Company, L.L.C.
4502 Woodland Corporate Boulevard
Tampa, FL 33614

B. Company Contact

Thomas J English
Director, Regulatory Affairs
Phone: 813-887-2170
Fax: 813-887-2413

C. Device Name

Trade Name:	DINAMAP® Pro 1000 Monitor
Common Name:	Physiological or Vital Signs Monitor, Patient Monitor
Classification/ Device Product Code:	System, Measurement, Blood Pressure, Noninvasive-870.1130-DXN Computer, Blood Pressure-870.1110-DSK Alarm, Blood Pressure-870.1100-DSJ Oximeter-870.2700-DQA Oximeter, Ear-870.2710-DPZ Thermometer, Clinical Electronic-880.2910-FLL Monitor, Cardiac (including cardiotachometer & rate alarm)-870.2300-DRT Electrocardiograph-870.2340-DPS Adapter, Lead Switching, Electrocardiograph-870.2350-DRW Monitor, Breathing Frequency-868.2375-BZQ Recorder, Paper Chart-870.2810-DSF

D. Predicate/Legally Marketed Devices

DINAMAP® MPS™ Select™ Portable Monitor-K971569 & K982342
Johnson & Johnson Medical Inc./ Critikon Inc.

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CRITIKON COMPANY, L.L.C.
4502 Woodland Corporate Blvd. • Tampa, FL 33614 • 813-887-2000 • www.dinamap.com

E. Device Description

The DINAMAP® Pro 1000 Monitor is intended to monitor a single patient's vital signs in the hospital, outpatient surgery and healthcare practitioner facilities. The patient populations include adult, pediatric, and neonatal. The device's networking capabilities include connection to a central station via VHF, 900 MHz or hardwire communication; host communications for use with other devices. In addition, the DINAMAP Pro 1000 Monitor may be operated from internal batteries making the device portable and suitable for intra-hospital transport.

F. Intended Use

The DINAMAP Pro 1000 Vital Signs Monitor is intended to monitor oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, oxygen saturation (SpO_2) by non-invasive pulse oximetry, and predictive temperature with an electronic thermometer in the adult, pediatric and neonate populations. The Pro 1000 Monitor also detects alarm limit conditions and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

G. Technological Characteristics

The DINAMAP® Pro 1000 Monitor has the same technological characteristics as the predicate device, the DINAMAP® MPS™ Select ™ Portable Monitor. There are no new technological characteristics. The Pro 1000 and MPS™ Select™ Portable monitors are both software-driven electronic devices which have the same monitoring parameters.

H. Parameter Technology

The DINAMAP® Pro 1000 Monitor has the following parameter technologies:

- NIBP algorithm tested according to the ANSI/AAMI SP10 standard.
- Wholly implemented Alaris thermometry technology
- Wholly implemented Nellcor Puritan Bennett SpO2 technology
- ECG/Respiration algorithm derived from the DINAMAP MPS® Select® Portable

I. Testing

Clinical studies were conducted to demonstrate performance (safety and effectiveness) of the DINAMAP® Pro 1000 Monitor to the ANSI/AAMI SP10 Standard: American National Standard for Electronic or Automated Sphygmomanometers.

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J. Testing cont.

Several bench studies were conducted which demonstrate safety and effectiveness of the DINAMAP® Pro 1000 Monitor:

- Mechanical and Environmental
- Electromagnetic Compatibility
- Battery Power
- Altitude Testing
- Electrical Safety
- ANSI/AAMI EC13

K. Substantial Equivalence

Pro 1000	Predicate Device & Model	**510(k) Numbers**
Monitor	DINAMAP MPS Select Portable Monitor	K971569
ECG	DINAMAP MPS Select Portable Monitor	K971569
Respiration	DINAMAP MPS Select Portable Monitor	K971569
Temperature	•Alaris Medical System, IVAC thermometry • DINAMAP Pro Series Monitor	K860436 K992638
NIBP	DINAMAP MPS Select Portable Monitor	K971569
SpO2	• Nellcor Puritan Bennett N-3000 Pulse Oximeter • DINAMAP Pro Series Monitor	K942347 K992638

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2000

Mr. Thomas J. English
Director, Regulatory Affairs
Critikon Company, L.L.C.
4502 Woodland Corporate Boulevard
Tampa, FL 33614

Re: K002248
Trade Name: Critikon DINAMAP Pro 1000 Monitor
Regulatory Class: II (two)
Product Code: DXN, DSK, DSJ, DQA, FLL, DRT, BZQ, DSF
Dated: July 18, 2000
Received: July 25, 2000

Dear Mr. English:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4346. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Health
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

July 18 , 2000

510(K) Number (if known): K002248

Device Name: DINAMAP® Pro 1000 Monitor

Indications for Use:

The DINAMAP Pro 1000 Vital Signs Monitor is intended to monitor oscillometric non-invasive blood pressure (systolic, diastolic and mean arterial pressure), heart/pulse rate, respiration rate, ECG, oxygen saturation (SpO_2) by non-invasive pulse oximetry, and predictive temperature with an electronic thermometer in the adult, pediatric and neonate populations. The Pro 1000 Monitor also detects alarm limit condition and is capable of recording up to two waveforms. Using this monitor a clinician can view, record and recall clinical data derived from each parameter.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002248

Prescription Use _____ or Over-The Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)